

REMARKS

The Office Action mailed August 15, 2007 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Applicant notes with appreciation the Examiner's withdrawal of the anticipation rejection of claims 1-8 and 13-23. Claims 1-5, 7-8, and 10-34 are pending in this application. No amendments are made herein.

Claim Rejections - 35 U.S.C. § 103

Claims 1-5, 7-8, 10-32 and 34-36 stand rejected under 35 USC § 103(a) as being unpatentable over USPAPN 2002/0016597 to Dwyer (hereinafter, "Dwyer") in view of USPN 5,690,643 to Wijay (hereinafter, "Wijay"). Claim 33 stands rejected under 35 USC § 103(a) as being unpatentable over Dwyer and Wijay as applied to claim 24, and further in view of USPN 5,458,615 to Klemm. Applicant respectfully traverses these rejections.

The rejection of independent claims 1 and 24 under 35 USC § 103(a) over Dwyer in view of Wijay was addressed in the previous response (i.e., the Amendment filed May 7, 2007) by Applicant. In summary, Applicant argued that a *prima facie* case of obviousness could not be established at least because Dwyer teaches away from the proposed combination and when Dwyer and Wijay are considered as a whole, there is no desirability for the proposed modification. This assertion was buttressed by Applicant using statements directly from the cited art with respect to the described structural and operational aspects thereof. In response, the Office Action states the following:

[t]he examiner disagrees and maintains the position that it would have been obvious to modify Dwyer with Wijay. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. As maintained above, Wijay teaches that an open coil permits the benefits of increased perfusion...and it would have been obvious to one of ordinary skill

in the art at the time of the invention to provide an open-coil structure, as taught by Wijay, to Dwyer in order to permit perfusion and reduce patient discomfort, and therefore there is a motivation to combine Wijay with Dwyer. (Office Action, pp. 8-9)

Applicant respectfully submits that, despite the rationale provided in the Office Action, the Office has yet to establish a *prima facie* case of obviousness. Specifically, the combination of Dwyer in view of Wijay is deficient in view of at least the MPEP guidelines reproduced below and the rationale provided in the Office Action does not appear to address these deficiencies. Therefore, Applicant requests withdrawal of the rejection and allowance of the pending claims.

Beginning in § 2141, the MPEP sets forth guidelines for rejections under 35 U.S.C. § 103. In § 2141.02, the MPEP states that “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention (citations omitted).” (MPEP § 2141.03, p. 2100-124, Eighth Edition, Rev. 5, August 2006, emphasis in original). Further, in § 2143.01, the MPEP states “[i]f the proposed modification or combination of prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious (citations omitted).” (MPEP § 2143.01, p. 2100-130, Eighth Edition, Rev. 5, August 2006). Also, in § 2145, the MPEP states that “[it] is improper to combine references where the references teach away from their combination (citations omitted).” (MPEP § 2145, p. 2100-160, Eighth Edition, Rev. 5, August 2006).

In determining the differences between the prior art and the claims, the prior art references must be considered in their entirety. Considering Dwyer and Wijay in their entireties reveals quite dissimilar devices. Dwyer shows and describes a deployment device in which the stent is deployed by holding an inner shaft 12 in a fixed position and sliding the distal end of an outer sheath proximal, relative to the distal end of the inner shaft (Dwyer, paragraph [0050], FIGS. 5-7). Wijay, to the contrary, shows and describes a deployment device in which the distal end of an inner tube is attached to the distal end of an outer tube such that deployment occurs either by pulling

the inner tube in a proximal direction, which causes the outer tube to bend (Wijay, col. 3:1-15, FIGS. 1, 2), and/or by twisting the outer tube with respect to the inner tube, which causes a coil to increase its diameter (Wijay, col. 4:33-50, FIG. 5).

When taken as a whole, the dissimilarity between the devices disclosed in Dwyer and Wijay is especially pertinent to the coil feature described in each. Dwyer describes a coil that is utilized to transfer compressive forces to the inner shaft that occur *due to the proximal withdrawal of the outer shaft*. As such, Dwyer specifically states that there are to be “no gaps between the coil members” (Dwyer, paragraph [0039]). Wijay, on the other hand, describes a coil that is attached to the distal end of the outer tube, thereby itself *forming a part of the outer tube*. As such, Wijay describes a coil that opens to permit perfusion as it increases in diameter. Thus, where Dwyer teaches a coil that cannot change in configuration during operation, Wijay teaches a coil that must change in configuration during operation.

Consequently, the proposed modification to replace the Dwyer closed coil structure with the Wijay open-coil structure would unquestionably change the principle of operation of the Dwyer delivery apparatus at least because providing gaps in the Dwyer coil would alter the operation and purpose of the coil, which is designed to transfer compressive forces during proximal withdrawal of the outer sheath. Accordingly, the asserted combination of Dwyer and Wijay do not render the claims *prima facie* obvious pursuant to MPEP § 2143.01.

Further, the proposed modification to substitute the Wijay open-coil structure for the Dwyer closed coil structure *teaches away* from the clear teaching of Dwyer. Dwyer describes the structure of the inner shaft in paragraph [0039] (underlining added for emphasis):

As seen from FIGS. 2, 3 and 10, the body portion 22 of the shaft 12 is made from a flexible coiled member 24, similar to a closed coil or compressed spring....Because the stent 100 is self-expanding it is in contact with the sheath 14 and the forces are transferred along the stent 100 and to the stop 40 of the shaft 12. This results in the shaft 12 being under

compressive forces. When this happens, the flexible coiled member 24 (no gaps between the coil members) transfers the compressive force from one coil to the next.”

As discussed by the Supreme Court in the recently decided case *KSR Int’l Co. v. Teleflex, Inc.*, “when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious” (550 U.S. ____ (2007), 82 USPQ2d 1385, 1395 (2007), quoting *United States v. Adams*, 383 U.S. 39, 40, 148 USPQ 479 (1966)). Dwyer clearly teaches away from the proposed modification of replacing the closed coil structure with an open-coil structure. Accordingly, it is improper to combine Dwyer and Wijay pursuant to MPEP § 2145 and the case law with respect to rejections under 35 U.S.C. § 103.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 480052000900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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